UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,952	10/12/2000	Jerry Pelletier	21715/1010	7855

29933 7590 07/26/2004

PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/689,952	PELLETIER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-33,35 and 53-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-33,35 and 53-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 26-33, 35 and 53-74 are pending.

Applicants' amendment and Declaration of Dr. Jerry Pelletier filed April 29, 2004 are acknowledged. Applicants' response and Dr. Jerry Pelletier's Declaration have been fully considered. Claims 26, 29, 31, 32, 35, 53, 57, 59, 63 and 65-67 have been amended, and a new claim 74 has been added. Thus, claims 26-33, 35 and 53-74 are examined.

Objection Withdrawn

2. The previous objection to the specification regarding the web address and Table 1 is withdrawn in view of applicant's amendment to the specification, and applicants' response at page 14 in the amendment filed April 29, 2004.

3. The previous objection to the drawings is withdrawn in view of the newly submitted Figs. 2, 6, 11, 12 and 14, however, this set of drawings does not contain all the figures. Please submit a complete set of formal drawings.

4. The previous objection to claims 26-33, 35 and 53-66 is withdrawn in view of applicant's amendment to the claims, and applicants' response at page 14 in the amendment filed April 29, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

5. The previous rejection of claim 29, 31-33, 35, 57 and 63 under 35 U.S.C. 112, second paragraph, regarding the term "a fragment or derivative of a bacteriophage inhibitor protein" or

the claim lacking essential steps, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 23 in the amendment filed May 03, 2004.

Informalities

The disclosure is objected to because of the following informalities:

6. An abstract has been submitted, however, the abstract of the disclosure does not commence on "a separate sheet" in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 26-33, 35, 53-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium, staphylococcus aureus (S. aureus) *in vitro*, comprising contacting the bacterium with a specific inhibitor such as bacteriophage 77 ORF 104 peptide (SEQ ID NO:5) which binds to or decreases the activity of a DnaI polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants, does not reasonably provide enablement for a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium, comprising contacting the bacterium with an inhibitor which binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants, or a method of treating or preventing (not even occurs at the first time) a bacterial infection in an animal, comprising administering an inhibitor or

antibacterial agent which binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants, where the structure of the inhibitor or antibacterial agent is not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 26-33, 35, 53-74 are directed to a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium, comprising contacting the bacterium with an inhibitor which binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants (claims 26-30, 65-74) or a method of treating or preventing a bacterial infection in an animal, comprising administering an inhibitor which binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants (claims 31-33, 35, 53-64). The specification, however, only discloses cursory conclusions (pages 4 and 7-9) without data supporting the findings, which state that the present invention relates to a pair of interacting proteins, a growth-inhibitory bacteriophage 77 ORF 104 gene product that interacts with S. aureus DnaI polypeptide, the interacting regions of the S. aureus DnaI related protein and the protein encoded by the bacteriophage 77 ORF 104, forming the basis for screening assays to identify a compound that is active on a polypeptide comprising the amino acid sequence of SEQ ID NO:16, and for a method of inhibiting a bacterium, or treating or preventing a bacterial infection in an animal using the compound. There are no indicia that the present application enables the full scope in view of a method of inhibiting bacterial growth of a bacterium, or treating or preventing a bacterial infection in an animal using an inhibitor that binds to or

decreases the activity of a polypeptide comprising SEQ ID NO:16, or its functional fragments or variants as discussed in the stated rejection. The present application does not provide sufficient teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breadth of the claims, the presence or absence of working examples, the state of the prior art and relative skill of those in the art, the predictability or unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the inhibitor that binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants; and the treating conditions and the effects of the inhibitors in a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium either *in vitro* or *in vivo*, or of treating or preventing a bacterial infection in an animal, which are not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

The specification indicates expression of bacteriophage 77 ORF 104 inhibits bacterial growth and identifies its nucleotide and amino acid sequences (Example 1, Fig. 4); the S. aureus DnaI homolog is identified as the host target of bacteriophage 77 ORF 104 (Example 2); and the specific domain of S. aureus DnaI (residues of 150-313 of SEQ ID NO:2, SEQ ID NO:16; or residues of 64-313 of SEQ ID NO:2, SEQ ID NO:18) or the proteolytic fragments of SEQ ID

NO:2 are identified as regions interacting with bacteriophage 77ORF104 (Example 3, Fig. 14C). However, there are no other working examples indicating the effects of various inhibitors in the claimed methods either *in vitro* or *in vivo*.

(3). The state of the prior art and relative skill of those in the art:

The related art (references shown at pages 2-3 of the specification) indicates S. aureus has been successfully treated with the penicillin derivative Methicillin in the past, but it is now becoming increasingly resistant, and it is not uncommon to isolate S. aureus strains which are resistant to most of the standard antibiotics, thus there is a need for new anti-microbial agents for this organism. However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the treating conditions and the effects of various inhibitors in a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium, or of treating or preventing a bacterial infection in an animal to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass many structural variants of the inhibitors that bind to or decrease the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants, but the effects of various inhibitors in the claimed methods either *in vitro* or *in vivo* are not demonstrated in the specification, the invention is unpredictable regarding the effects of various inhibitors in inhibiting bacterial growth or bacterial DNA synthesis of a bacterium *in vivo*, or treating or preventing a bacterial infection in an animal.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium or treating or preventing a bacterial infection in an animal, comprising contacting the bacterium with an inhibitor or administering an inhibitor to the animal which binds to or decreases the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants. The specification indicates the invention is based on the discovery that DnaI is a target for the bacteriophage 77 ORF 104 inhibitory factor, and the interaction between these two proteins is useful in the development of antibacterial agents, e.g., DnaI as a target for bacterial inhibition; phage 77ORF104 or derivative or functional mimetic thereof as agents for inhibiting bacterial growth; and the interaction between DnaI of S. aureus and 77ORF104 used as a target for screening and rational design drugs or antibacterial agents (last paragraph at page 67). The specification also indicates expression of bacteriophage 77 ORF 104 inhibits bacterial growth (Example 1, Fig. 4); the S. aureus DnaI homolog is identified as the host target of bacteriophage 77 ORF 104 (Example 2); and the specific domain of S. aureus DnaI (residues of 150-313 of SEQ ID NO:2, SEQ ID NO:16; or residues of 64-313 of SEQ ID NO:2, SEQ ID NO:18) and the proteolytic fragments of SEQ ID NO:2 are identified as the region interacting with bacteriophage 77ORF104 (Example 3, Fig. 14C). However, the specification has not demonstrated various inhibitors that bind to or decrease the activity of a polypeptide comprising SEQ ID NO:2, SEQ ID NO:16, or SEQ ID NO:18, or its functional fragments or variants in the claimed method except for expression of 77 ORF 104 peptide inhibiting the growth of S. aureus *in vitro*, and there are no working examples indicating the claimed methods associated with various inhibitors *in vivo*. Moreover, the specification has not described how to extrapolate the *in vitro* data to *in vivo* effect in the

treatment. Furthermore, the specification has not indicated the treating conditions such as the amount of inhibitor used for preventing the bacterial infection, and how to monitor the effect of inhibitor if the infection is prevented to occur. Since the specification does not provide sufficient teachings in the method of inhibiting bacterial growth or bacterial DNA synthesis of a bacterium or of the treatment or prevention of bacterial infection using various inhibitors, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of inhibitors in inhibiting bacterial growth or bacterial DNA synthesis of a bacterium or in the treatment or prevention of bacterial infection. The experimentation is undue because it is required further research to obtain the effective amount of various inhibitors having different structures for in vivo inhibiting bacterial growth, or treatment or prevention of bacterial infection.

(6). Nature of the Invention

The scope of the claims includes many structural variants of inhibitors, however the specification has not provided sufficient teachings on the treating conditions, nor has demonstrated the effectiveness of various inhibitors in the claimed methods. Thus, the disclosure is not enabling for reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the claimed methods associated with variants, and the teaching in the specification is limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of inhibitors in inhibiting bacterial growth or bacterial DNA synthesis of a bacterium, or in the treatment or prevention of bacterial infection.

In response, an amendment and Declaration of Dr. Jerry Pelletier have been filed. In the Declaration of Dr. Jerry Pelletier, paragraphs 5 and 6 state an additional phage polypeptide, PVLORF16 was identified and found to be a cytostatic inhibitor (see Annex II-A), subsequently to the identification of 77ORF104 (the bacterial growth inhibitory bacteriophage polypeptide that binds to DnaI). PVLORF16 binds to *S. aureus* DnaI when expressed in the yeast two-hybrid system, and it inhibited DNA synthesis (see Annex II-B); and paragraph 7 indicates these results confirm additional bacterial growth inhibitory bacteriophage polypeptides binding to and inhibiting activity of *S. aureus* DnaI can be readily identified using the method of the present invention.

In the response, applicants indicate that the specification provides sufficient disclosure to enable one of skill in the art to make and use of the claimed invention without undue experimentation. Applicants further assert that the specification provides a novel pathway by which bacterial infections can be prevented and/or treated, it also provides a new bacterial protein (DnaI polypeptide) useful in the development of antibiotics as well as inhibitors binding to and reducing the activity of the bacterial protein thereby reducing bacterial growth. Identification of additional inhibitors using the teachings of the present application is within the skilled of those in the art and does not require undue experimentation as explained at pages 15-23 of the response and as evidenced by the additional results presented in the Rule 132 Declaration (Dr. Jerry Pelletier's Declaration), and in Liu et al. (Nature Biotechnology (2004) Vol. 22 pages 185-191). Applicant's response and Dr. Jerry Pelletier's Declaration have been considered, however, the argument is not fully persuasive because the specification only teaches expression of bacteriophage 77 ORF 104 (SEQ ID NO:5) inhibits bacterial growth and various

assay methods to monitor the potency of the inhibitor in binding to and reducing the activity of DnaI polypeptide, it has not identified various inhibitors with different structures, which bind to and reduce the activity of DnaI polypeptide, nor has demonstrated various inhibitors in an amount effective to inhibit bacterial growth either *in vitro* or *in vivo*, or to treat or prevent a bacterial infection in mammals, which are encompassed by the claimed methods. Furthermore, Dr. Jerry Pelletier's Declaration and Liu et al. (Nature Biotechnology Vol. 22 pages 185-191 (2004), a post filing reference) indicate inhibitory activities of PVLORF16 (a bacteriophage polypeptide) and two organic compounds against S. aureus *in vitro*, however, there are no data indicating these inhibitors in an amount effective to inhibit bacterial growth *in vivo*, or to treat or prevent a bacterial infection in mammals. Furthermore, the specification has not taught how to extrapolate the *in vitro* data to *in vivo* effect in the treatment, nor has demonstrated the use of effective doses for various inhibitors having different structures in inhibiting bacterial growth *in vivo* or in the treatment or prevention of bacterial infection. Thus, it requires undue experimentation to identify various inhibitors effective for in vivo treatment, the experimentation is undue because it requires further research to practice the claimed invention.

Regarding the Wands factors, applicants indicate the breadth of the claims encompass inhibitors inhibiting bacterial growth by binding to or by decreasing the activity of DnaI, and the invention, does not rely solely on a specific type of compound that could be used to carry out the claimed method. By identifying a new bacterial protein target (*S. aureus* DnaI) for inhibiting bacterial growth, the present inventors have made a "pioneer" invention. Based on well settled law, the Applicants are entitled to broad claim scope commensurate with the magnitude of the scientific achievement advanced in the present application. Thus, given the pioneer status of the

present invention, coupled with (1) the disclosure of a specific inhibitor of S. aureus DnaI (i.e., bacteriophage 77 ORF104), (2) the disclosure of methods for identifying and testing additional candidate inhibitors (pages 67-91), and (3) the post-filing discoveries of additional inhibitors of S. aureus DnaI, i.e., PVLORF16 (Declaration of Dr. Jerry Pelletier and Annex 2), and two small compounds (Liu et a1., Nature Biotechnology (2004) Vol. 22 pages 185-191), the full scope of the invention is enabled without undue experimentation (pages 16-20 of the response); The level of skill in the art with respect to the particular techniques and laboratory methods needed to carry out the identification of an inhibitor useful in the claimed methods is high. Thus, one of skill in the art could readily follow the teachings provided by the instant specification to conduct experiments to identify additional inhibitors used for the claimed methods (pages 20-21); the claims have been amended to recite that the inhibitor inhibits or reduces bacterial growth. Thus, the invention is not unpredictable regarding the effects of various inhibitors in inhibiting bacterium because the inhibitors for use in the invention are selected precisely based on their ability to inhibit bacterial growth (page 21); The specification provides the teaching for identifying additional inhibitors. Although it may be necessary to carry out further experimentation to assess the effects of potential inhibitors against bacterial growth or in the course of the treatment of bacterial infection, these experiments are well within the realm of routine experimentation and do not require undue experimentation as evidenced by the data presented in the Rule 132 Declaration and in the Liu et al. reference. With respect to the Examiner's assertion that the specification does not teach how to assess the effects of inhibitors in inhibiting bacterium or in the treatment of bacterial infection, or how to monitor the effect of inhibitor in the prevention of infection, Applicants submit that such methods were routine in the

art at the time of the filing of the subject application. Thus, there is no undue experimentation required to assess the effects of inhibitors in inhibiting bacterium or in the treatment of bacterial infection (pages 21-23).

Regarding applicants' suggestion of considering the present invention as a "pioneer status", so applicants are entitled to broad claim scope. The argument is not found persuasive because MPEP 2164.08 states alleged "pioneer status" of the invention is irrelevant to enablement determination (see below). Thus, the issue of treating the present invention as a "pioneer status" is not considered here.

> As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). >See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination).<

The response to the analysis of Wands factors has been considered, however, the argument is not found persuasive because of the following reasons: The disclosure of a specific inhibitor of S. aureus DnaI and the methods for identifying and testing additional candidate inhibitors in the specification as well as the post-filing discoveries of additional inhibitors of S. aureus DnaI in the Declaration of Dr. Jerry Pelletier and Liu *et al.* (2004) only indicate the use of certain inhibitors of S. aureus DnaI for inhibiting bacterial growth *in vitro*, there are no data indicating the *in vivo* treatment using effective amounts of various inhibitors, and no teachings regarding the extrapolation of *in vitro* data to *in vivo* effect; Since the specification does not demonstrate various inhibitors of *S. aureus* DnaI inhibit bacteria growth either *in vitro* or *in vivo*, and many method claims (e.g., claims 26-30 and 53-73) do not cite the limitation "the inhibitors

inhibit bacterial growth", thus, the effects of various inhibitors are not predictable in the claimed methods without further experimentation; and applicants indicate the methods of assessing the effects of various inhibitors of *S. aureus* DnaI in inhibiting bacterium *in vivo* or in the treatment of bacterial infection, and methods of monitoring the effect of inhibitor in the prevention of infection are routine methods, however, no references have been provided. Furthermore, the disclosure has not identified various inhibitors of *S. aureus* DnaI with different structures, nor has demonstrated effective amounts of various inhibitors in the method of inhibiting bacterial growth *in vivo*, or of treating or preventing a bacterial infection in mammals as encompassed by the claimed methods. Thus, it is necessary to carry out further experimentation to practice the claimed methods, the experimentation is undue because further research is required for identifying various effective inhibitors and the treating conditions such as doses for *in vivo* treatment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26-30 and 53-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 26-30 and 53-73 are indefinite because the claim lacks an essential step in the method of inhibiting a bacterium or treating a bacterial infection. The omitted step is the outcome of the treatment for claims 26-30 and 53-73. Claims 27-30, 54-58, 60-64 and 68-73 are

included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the claims have been amended to cite "effective amount" for the amount of inhibitor, and "inhibition of bacterial growth" or "thereby preventing said infection" for outcome of the treatment. The response has been considered, however, the argument is not fully persuasive because claims 26, 53, 59 and 67 do not cite the outcome of the treatment, the claim only indicates an amount of inhibitor effective to reduce the activity of the polypeptide, it does not indicate the inhibitor inhibits bacterial growth; and claim 65 and 66 cite "a decrease of said activity reduces bacterial growth", which does not indicate the effect of treatment using the inhibitor, it is not clear whether the inhibitor is effective in treating or preventing infection.

Conclusion

10. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
July 16, 2004

Supervisory Jon P. Weber, Ph.D.
Primary Examiner